

Decision Memo for Human Chorionic Gonadotropin (Addition of ICD-9-CM Code 158.9, Malignant Neoplasm of Peritoneum, Unspecified) (CAG-00372N)

Decision Summary

CMS has determined that ICD-9-CM diagnosis code, 158.9, Malignant neoplasm of peritoneum, unspecified, flows from the existing narrative for conditions for which a human chorionic gonadotropin (hCG) test is reasonable and necessary. Consequently, ICD-9-CM diagnosis code 158.9 shall be added to the list of "ICD-9-CM Codes Covered by Medicare Program" for the national coverage determination (NCD) for hCG testing, as stated in Section 190.27 of the NCD Manual.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-04, Chapter 16, Section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

TO: Administrative File: CAG-00372N
Human Chorionic Gonadotropin (Addition of ICD-9-CM Code 158.9, Malignant Neoplasm of Peritoneum, Unspecified)

FROM:

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SUBJECT: Human Chorionic Gonadotropin (Addition of ICD-9-CM Code 158.9, Malignant Neoplasm of Peritoneum, Unspecified)

DATE: February 16, 2007

I. Decision

CMS has determined that ICD-9-CM diagnosis code, 158.9, Malignant neoplasm of peritoneum, unspecified, flows from the existing narrative for conditions for which a human chorionic gonadotropin (hCG) test is reasonable and necessary. Consequently, ICD-9-CM diagnosis code 158.9 shall be added to the list of "ICD-9-CM Codes Covered by Medicare Program" for the national coverage determination (NCD) for hCG testing, as stated in Section 190.27 of the NCD Manual.

II. Background

Human Chorionic Gonadotropin (hCG) testing is used for monitoring and diagnosing germ cell neoplasia. hCG may also be used to monitor pregnancy in patients who experience hypertension, vaginal bleeding, or suspected fetal loss.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled, "ICD-9-CM Codes Covered by Medicare Program," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled, "ICD-9-CM Codes Denied," and lists diagnosis codes that are never covered by Medicare. The third list is entitled, "ICD-9-CM Codes that Do Not Support Medical Necessity," and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

IV. Timeline of Recent Activities

On January 26, 2007, CMS formally accepted a request for consideration to add ICD-9-CM diagnosis code 158.9 to the list of diagnosis codes covered by Medicare for the hCG testing NCD.

We posted a tracking sheet to the Internet at <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=200>, and solicited public comments for 30 days on the appropriateness of the addition of code 158.9 to our hCG testing NCD.

We did not receive any comments during the comment period, which ended on February 12, 2007.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process that did not require scientific evidence. We call this abbreviated process the Coding Analysis for Laboratories (CAL) process.

VI. CMS Analysis

As noted above, we have taken the position that the "ICD-9-CM Codes Covered by Medicare Program" list is intended to contain only those codes that flow from the narrative of the indication in the NCD. CMS' hCG NCD states, in part, that hCG testing is indicated "for monitoring and diagnosis of germ cell neoplasms of the ovary, testis, mediastinum, retroperitoneum, and central nervous system."

Because germ cell neoplasia may exist within or spread into the peritoneum, and because there may be diagnostic benefit in distinguishing a peritoneum-located neoplasm as being a germ cell neoplasm, we believe that the ICD-9-CM code for malignant neoplasm of peritoneum, unspecified, flows from the existing narrative, quoted above, for conditions for which a human chorionic gonadotropin (hCG) test is reasonable and necessary. Consequently, ICD-9-CM diagnosis code 158.9 shall be added to the list of "ICD-9-CM Codes Covered by Medicare Program" for the national coverage determination (NCD) for hCG testing, as stated in Section 190.27 of the NCD Manual.

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